

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

MARY HORSMON and)	
FRED HORSMON)	
)	
Plaintiffs,)	
)	Civil Action No. 11-1050
v.)	
)	Judge Cathy Bissoon
ZIMMER HOLDINGS, INC., <i>et al.</i> ,)	
)	
Defendants.)	

MEMORANDUM AND ORDER

I. MEMORANDUM

Pending before the Court is Defendants Zimmer Holdings, Inc., Zimmer Inc., and Zimmer US, Inc.'s Partial Motion to Dismiss Plaintiffs' Complaint (Doc. 12). For the reasons stated herein, the Court will grant Defendants' motion to dismiss.

BACKGROUND

A. Factual Background

In May 2006, Plaintiff Mary Horsmon had a total hip replacement whereby her right hip joint was replaced with implant components designed, manufactured, and sold by Defendants. Compl. ¶¶ 11-12 (Doc. 1-2). Ms. Horsmon later began to experience pain in her right hip. Id. at ¶ 13. Sometime in 2009, an X-ray revealed that the screw holding Ms. Horsmon's hip prosthesis in place was broken, and that the hip implant system had shifted from its original position. Id. In September 2009, Ms. Horsmon underwent a revision of her total hip replacement, in which her doctor removed the broken screw and replaced several components of the hip implant. Id. at ¶ 15. Post-operative X-rays indicated that a portion of the broken screw remained in Ms. Horsmon's pelvis, and a subsequent pathology report revealed a 3.0 cm defect in the original liner that was used during the May 2006 hip replacement. Id. at ¶ 16.

Plaintiffs allege that Defendants' conduct caused Ms. Horsmon to suffer various injuries, including being forced to undergo a second major surgical procedure, permanent injury to her hip, and severe pain and discomfort. Id. at ¶ 17.

B. Procedural Background

Plaintiffs brought this action in the Court of Common Pleas of Allegheny County, asserting five causes of action: negligence (Count I); strict liability (Count II); breach of implied warranties (Count III); breach of express warranties (Count IV); and loss of consortium (Count V).¹ Defendants removed this action to this Court on the basis of diversity jurisdiction under 28 U.S.C. § 1332, and filed the currently pending motion to dismiss Counts II, III and IV of Plaintiffs' complaint. Defendants assert that Counts II and III should be dismissed as barred by Pennsylvania law, and that Count IV should be dismissed for failing to allege sufficient facts to state a plausible claim.

ANALYSIS

A. Strict Liability (Count II)

Defendants assert that Plaintiff's claim for strict liability (Count II) is barred by Pennsylvania law.² Defs.' Br. 4-5 (Doc. 13). The Supreme Court of Pennsylvania in Hahn v. Richter, 673 A.2d 888 (Pa. 1996), held that strict liability claims cannot be brought against prescription drug manufacturers. The court relied on Comment k to the Restatement (Second) of Torts § 402A. Comment k, titled "Unavoidably unsafe products" states:

¹ Plaintiff Fred Horsmon is Ms. Horsmon's husband. See Compl. ¶ 48. Counts I-IV are brought by Ms. Horsmon, and Count V is brought by Mr. Horsmon. Because only Counts II-IV are at issue in Defendants' motion to dismiss, references to "Plaintiff" in this opinion refer to Ms. Horsmon.

² The parties agree that Pennsylvania law applies to Plaintiffs' claims. See Defs.' Br. 4 n.1 (Doc. 13); Pl.'s Br. 3, 8, 10 (Doc. 18).

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Comment k does not mention medical devices and the Supreme Court of Pennsylvania has not addressed whether Hahn applies to medical device manufacturers, but the Superior Court of Pennsylvania and several United States District Courts applying Pennsylvania law have extended Hahn to bar strict liability claims against medical device manufacturers. *E.g.*, Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (“We find no reason why the same rational [sic] applicable to prescription drugs [in Hahn] may not be applied to medical devices.”); Parkinson v. Guidant Corp., 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (Diamond, J.); Kester v. Zimmer Holdings, Inc., 2:10-cv-523, 2010 WL 2696467, at *9 (W.D. Pa. June 16, 2010) (McVerry, J.); Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 749-50 (E.D. Pa. 2007). This Court agrees that the reasoning of Hahn extends to medical devices.

Plaintiff argues that even if Hahn applies to medical device manufacturers, numerous commentators and courts have recognized the caveat in Comment k that a drug manufacturer is shielded from strict liability claims only if its product is “properly prepared, and accompanied by proper directions and warning.” Pl.’s Br. 4-5 (Doc. 18). Plaintiff only cites law from other jurisdictions. *See id.* But Hahn is the law of Pennsylvania, and the court in Hahn did not

recognize this caveat in Comment k. See Hahn, 673 A.2d at 891 (“[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer’s negligence, is the only recognized basis of liability.”). Other courts have interpreted Hahn as imposing an absolute bar to strict liability claims against both prescription drug manufacturers and medical device manufacturers. See Parkinson, 315 F. Supp. 2d at 747-48 (finding that while Comment k contains caveats, “the Pennsylvania Supreme Court [in Hahn] ruled that § 402A strict liability is precluded entirely for prescription drugs, and, presumably by extension, prescription medical devices”); Soufflas, 474 F. Supp. 2d at 749 n.8 (“Under Pennsylvania law, . . . strict liability and § 402A are inapplicable to prescription drugs.”); Bearden v. Wyeth, 482 F. Supp. 2d 614, 618 n.5 (E.D. Pa. 2006) (noting that while Arkansas recognizes caveats in Comment k, Pennsylvania does not). While other jurisdictions might recognize caveats to Comment k’s exclusion of strict liability claims, this Court must apply Pennsylvania law, which does not recognize such caveats. Plaintiff’s claim for strict liability is precluded by Pennsylvania law, and Count II of Plaintiffs’ complaint is dismissed for failure to state a claim.

B. Breach of Implied Warranties (Count III)

Defendants assert that Plaintiff’s breach of implied warranties claim (Count III) also is barred by Pennsylvania law. In a claim for breach of implied warranty of merchantability, “[t]he essence of the warranty of merchantability is that the item sold is fit for the ordinary purposes for which such goods are used.” Makripodis v. Merrell-Dow Pharms., Inc., 523 A.2d 374, 376 (Pa. Super. Ct. 1987) (citing Wisniewski v. Great Atl. & Pac. Tea Co., 323 A.2d 744, 746-47 (Pa. Super. Ct. 1974); 13 Pa.C.S. § 2314(b)(3)). Under Pennsylvania law, “the very nature of prescription drugs themselves precludes the imposition of a warranty of fitness for ‘ordinary purposes’, as each individual for whom they are prescribed is a unique organism who must be

examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient.” Id. at 377. Breach of implied warranty of merchantability claims, therefore, are precluded for prescription drugs. Id.

Several courts have extended the reasoning of Makripodis to preclude claims against medical device manufacturers for breach of implied warranties of merchantability and fitness for a particular purpose. E.g., Parkinson, 315 F. Supp. 2d at 752-53 (finding that Pennsylvania law precludes claims for breach of implied warranties of merchantability and fitness for particular purpose for medical devices); Soufflas, 474 F. Supp. 2d at 751-52 (same); Kester, 2010 WL 2696467, at *11 (“As with strict products liability claims for failure-to-warn, Pennsylvania courts have held that the nature of prescription drugs *and* prescription medical devices precludes claims for breach of implied warranty.” (citing Parkinson, 315 F. Supp. 2d at 752-53)). Plaintiff argues that such reasoning is flawed, because Makripodis involved a consumer's claim against a retailer, not against a manufacturer. Pl.'s Br. 8-9 (Doc. 18). But the rationale in Makripodis relates to the nature of prescription drugs, not to the nature of the relationship between the plaintiff and the defendant. See Makripodis, 523 A.2d at 377. The reasoning in Makripodis, therefore, applies to manufacturers. This Court agrees with the various other courts that have found that Makripodis applies to both prescription drugs and medical devices.

Plaintiff also argues that the court in Makripodis misapplied Comment k to the Restatement (Second) of Torts § 402A in finding implied warranty claims precluded for prescription drugs. Pl.'s Br. 8-9 (Doc. 18). While the court in Makripodis cited Comment k in support of its reasoning, the court found that the nature of prescription drugs, not Comment k, precludes the imposition of a warranty of fitness for “ordinary purposes.” Makripodis, 523 A.2d at 377. Further, the Restatement (Second) of Torts is not law. Plaintiff has not pointed to

anything that would indicate that the Supreme Court of Pennsylvania would disagree with the Superior Court's finding in Makripodis, and this Court cannot rely on the Restatement (Second) of Torts to contradict a Pennsylvania state court decision. Finally, Plaintiff's reliance on law from other states is similarly unavailing. See Pl.'s Br. 10 (Doc. 18) (citing Illinois and New Mexico law).

Because Pennsylvania law precludes breach of implied warranty claims for medical devices, Count III of Plaintiffs' complaint is dismissed for failure to state a claim.

C. Breach of Express Warranties (Count IV)

Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa.C.S. § 2313(a). Defendants assert that Plaintiff's claim for breach of express warranty should be dismissed for failing to allege any facts to suggest that her claim is plausible. See Defs.' Br. 6-9 (Doc. 13).

In deciding a motion to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6), the Court must accept as true all factual allegations in the complaint and draw all inferences from the facts alleged in the light most favorable to the plaintiff. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008). To survive a motion to dismiss, the factual allegations in a complaint must "state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, ___, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citing Twombly, 550 U.S. at 556).

Plaintiff alleges that "Defendants expressly warranted in its written literature, advertisements and representations of its representatives and agents that its acetabular systems,

bone screws, liners and other related components were safe, effective, fit, and proper for the use for which they were intended.” Compl. ¶ 43 (Doc. 1-2). But Plaintiff has not alleged any particular “affirmation of fact or promise,” 13 Pa.C.S. § 2313(a), that would give rise to a reasonable inference that Defendants “expressly warranted” that its products “were safe, effective, fit, and proper for the use for which they were intended.” Compl. ¶ 43 (Doc. 1-2).³

Plaintiff’s allegations also do not support a reasonable inference that any affirmation of fact or promise by Defendants became “part of the basis of the bargain” in Plaintiff’s purchase of Defendants’ goods. 13 Pa.C.S. § 2313(a). Plaintiff alleges that she “relied on the skill and judgment and express warranties of Defendants that these products were safe, effective, fit and proper for the use for which they were intended.” Compl. ¶ 44 (Doc. 1-2). Of course, Plaintiff cannot allege that any particular affirmation of fact or promise became “part of the basis of the bargain” without alleging any particular affirmation of fact or promise. But even assuming Plaintiff sufficiently pled an affirmation of fact or promise, Plaintiff merely alleges that she “relied on” Defendants’ “express warranties.” Compl. ¶ 44 (Doc. 1-2). Plaintiff does not allege for what purpose she “relied on” the alleged “express warranties.” See *id.* Plaintiff’s factual allegations do not indicate whether her alleged reliance was part of her decision to purchase

³ Defendants argue that Plaintiff’s allegations do not “sufficiently identify the actual *source* of the alleged warranty as required to withstand a motion to dismiss under Pennsylvania law.” Defs.’ Br. 7 (Doc. 13). Defendants rely on Simmons v. Stryker Corp., No. 08-3451, 2008 WL 4936982, at *2 (D.N.J. Nov. 17, 2008), a non-binding case applying New Jersey law where the plaintiff identified “no source whatsoever of any alleged warranty.” Pennsylvania law applies to this case, and Plaintiff alleges that “written literature, advertisements and representations of [Defendants’] representatives” are the source of the express warranty. Simmons, therefore, is inapposite. As explained above, however, Plaintiff has failed to allege that any particular “affirmation of fact or promise” was made in any of those sources.

Defendants' products (i.e., that she relied on Defendants' promises as "part of the basis of the bargain").⁴

Because Plaintiff has not alleged sufficient facts to support a reasonable inference that Defendants made "[a]ny affirmation of fact or promise . . . which relates to the goods," and has not alleged sufficient facts to support a reasonable inference that any such affirmation of fact or promise became "part of the basis of the bargain," Plaintiff has failed to state a plausible claim for breach of express warranties under Pennsylvania law. 13 Pa.C.S. § 2313(a); See Kester, 2010 WL 2696467, at *11 (dismissing breach of express warranty claim where "Plaintiff neither specifies any particular promise that formed the basis of her bargain with the Defendants, who are generically and collectively named, nor does she demonstrate any promise was directed at her, as a consumer, to induce her into purchasing the product"). Count IV of Plaintiffs' complaint is dismissed for failure to state a claim.

CONCLUSION

For all of the reasons stated above, Defendants Zimmer Holdings, Inc., Zimmer Inc., and Zimmer US, Inc.'s Partial Motion to Dismiss Plaintiffs' Complaint (Doc. 12) is granted. Because Plaintiff's strict liability claim (Count II) and breach of implied warranties claim (Count III) are barred by Pennsylvania law, amendment to Counts II and III of Plaintiffs' complaint would be futile. Counts II and III, therefore, are dismissed with prejudice. See Phillips v. Cnty.

⁴ Defendants argue that Count IV should be dismissed because Plaintiff has not alleged that she actually saw, heard, or knew about a particular promise or representation made by Defendants. Defs.' Br. 8 (Doc. 13). Plaintiff alleges that she "relied on the . . . express warranties of Defendants" Compl. ¶ 44 (Doc. 1-2). Accepting this allegation as true, Plaintiff, by implication, must have seen, heard, or known about the alleged express warranties. The parties disagree as to whether a breach of express warranty claim under Pennsylvania law requires reliance on the part of the buyer. Compare Defs.' Br. 6 (Doc. 13), with Pl.'s Br. 10 (Doc. 18). Because Plaintiff alleges that she relied on Defendants' alleged express warranties, the Court need not determine at this time whether reliance is a required element of a breach of express warranty claim.

of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008) (“[I]n the event a complaint fails to state a claim, unless amendment would be futile, the District Court must give a plaintiff the opportunity to amend her complaint.” (citing Shane v. Fauver, 213 F.3d 113, 116 (3d Cir. 2000))). Plaintiff’s breach of express warranties claim (Count IV) is dismissed without prejudice.

II. ORDER

For the reasons stated above, the Court hereby **ORDERS** that Defendants Zimmer Holdings, Inc., Zimmer Inc., and Zimmer US, Inc.’s Partial Motion to Dismiss Plaintiffs’ Complaint (Doc. 12) is **GRANTED**. Plaintiff Mary Horsmon’s claims for strict liability (Count II) and breach of implied warranties (Count III) are **DISMISSED WITH PREJUDICE**. Plaintiff Mary Horsmon’s claim for breach of express warranties (Count IV) is **DISMISSED WITHOUT PREJUDICE**. If appropriate and consistent with Federal Rule of Civil Procedure 11, Plaintiffs may file an amended complaint for the limited purpose of amending Plaintiff Mary Horsmon’s breach of express warranties claim (Count IV) no later than November 21, 2011. If no amended complaint on Count IV is received by that date, it will be assumed that Plaintiff acknowledges that she cannot state a breach of express warranty claim and the claim will be deemed to have been dismissed with prejudice without further order of Court.

IT IS SO ORDERED.

s/ Cathy Bissoon
Cathy Bissoon
United States District Judge

November 10, 2011

cc (via e-mail):

All counsel of record.